Association of British Insurers

FEBRUARY 2016, VERSION 1.0

E-SIGNATURE CONSENT FOR OBTAINING INFORMATION FROM MEDICAL RECORDS

HIGH LEVEL PRINCIPLES

Background

In 2009 research by e-Commerce bodies, such as Origo, found that there was a reluctance to move away from the use of wet signatures as a means of obtaining consent for requesting medical underwriting data from GPs. However, work by Origo in 2014 showed that life and pension providers have moved forward significantly since then, introducing the use of e-Signatures for the servicing and sales of life and pension products and the development of extranets for use by advisers and direct clients alike. Insurers and pension providers see this as a way of providing advisers and clients with a better level of service and improving upon current safeguards around obtaining patients' medical information whilst also protecting the doctor-patient relationship.

This advance in the use of e-Signatures can also be seen by the growth in the use of the internet by consumers for the fulfilment of goods and services, which many of us now use instinctively, such as online shopping, banking and the management of household utilities.

The use of e-Signatures is now accepted in law as good for formation of a contract and details of the relevant legislation and case law can be seen in the Appendix 1.

There is evidence in the marketplace of several e-Signature initiatives for consent being developed. The ABI and BMA recognise the importance of establishing a common set of high level principles (principles) across the industry and its stakeholders to ensure that greater use of e-Signatures not only continues to protect patients and GPs, but that it also improves safeguards and speeds up the process for clients/patients, GPs and third parties. Without an agreed set of principles, it will become increasingly difficult to guarantee an industry standard that ensures the move to e-Signatures works for the benefit of clients/patients, GPs and those third parties, such as insurance providers, wishing to obtain medical information on behalf of their clients.

Failure to establish these principles, and not to do so whilst the use of e-Signatures is still in its early stages, may result in confusion, low uptake and, ultimately, a missed opportunity for everyone involved.

Failure to agree principles and safeguards could also result in mistrust between insurance providers and the medical profession, especially where there are already concerns about safeguards around obtaining patients' medical information as part of the Care.Data project. As such, these principles have been seen by the Joint GP IT Committee of the BMA and RCGP (JGPITC) and General Medical Council for their thoughts and input, both of whom are content with the safeguards and confidence they offer.

The Case for e-Signatures

To understand the need for change it is worth having a look at the existing consent process to help understand the problem from the point of view of GPs, insurance and pension providers and clients/patients.

Terms for life insurance and annuities are offered based on an actuarial assessment of risk. Where initial client disclosures, or the level of insurance being requested indicate the need for further medical information (typically around 30% of cases) providers seek medical information from the relevant GP to determine whether their client/patient has a higher or lower than normal risk of death or suffering from a critical illness or disability. Providers require consent from the client/patient to obtain that medical information. The current process is to ask the client direct or through their financial adviser, where one is involved, to provide their consent by signing a physical consent document e.g. an AMRA form.

From a GP's perspective, this means the need for handling paper requests for this medical data, signed by their patient. GPs must satisfy themselves that they have obtained satisfactory consent before passing medical information on their patients to third parties, which can be difficult in instances where the GP may not hold an original record of the patient's signature.

E-Signatures can both secure and speed up the process by allowing the consent to be sent instantly and electronically to the GP, thus cutting out several days from the process. However, GPs will not be obliged to have any specialist software or hardware in order to facilitate the use of e-Signature consent. Crucially, an e-Signature process can also improve upon current safeguards by ensuring an audit trail is made easily available to the GP to provide evidence that fully informed and clear consent has been obtained from their patient and is not fraudulent, without the need for the GP to make a comparison of wet-signatures held on file for every consent form.

From the third party point of view, such as an insurance provider, e-Signatures will allow them to provide insurance cover to their clients more quickly by reducing the time it takes for consent to get from client to insurer to GP, whilst protecting the GP's position.

High Level Principles

The aim of these Principles is to set an industry standard which allows new product providers and users of e-Signatures to innovate whilst maintaining safeguards and improving the current system for both patients and GPs, in terms of security, speed of access and transparency. They should provide confidence to patients and users and ensure that providers of e-Signature processes can take all reasonable steps to ensure data validity is obtained.

An e-Signature process should therefore adhere to the following Principles:

1. **Be legally compliant**
   The use of e-Signatures should fully comply with all relevant current (see Appendix) and future English and Scottish law

2. **Be compliant with ABI, BMA and GMC guidance and that of HSCIC and the ICO**
   The terms of these Principles will be incorporated into the ABI and BMA's joint guidance on access to medical information to make them easily accessible to Product Providers, GPs and patients. An e-Signature process will conform to Information Commissioner and Health and Social Care Information Centre guidance on their use.

3. **Conform to ISO/ BSI Standards or equivalent**
   A Product Providers e-Signature processes should conform to a minimum ISO/BSI certification standard e.g. ISO27001, or demonstrate a similar level of data security in their internal processing.

4. **Not compromise GPs' professional indemnity**
   The use of e-Signature processes conforming to these Principles should not compromise a GP's professional indemnity and should give GPs confidence.

5. **Be reviewed upon fundamental changes in legislation**
   The Principles should be reviewed by the ABI and the BMA formally upon implementation, if there are ever notable problems with the system and whenever relevant legislation, regulation or regulatory guidance is updated.

6. **The release of information remains entirely within the control of the GP practice**
   The release of information should always remain within the control of the GP practice and practice staff, whether with human authorisation or otherwise.

7. **Ensure the consent provided is fully informed**
   The e-Signature process must make it clear to the individual exactly what consent they are being asked to provide, and do so in an unambiguous, straightforward manner.

8. **Provide an audit trail of the consent process available to all parties**
   The e-Signature process should generate an audit trail that is readily available to both patient and GP. The audit trail should clearly show what consent was granted, by whom, when and why.

9. **Incorporate controls to confirm the identity of the signer**
   The e-Signature process must include controls to confirm the identity of the signing party sufficient that all parties can be confident in the process.

10. **Be at least as safe as the current system**
    The use of an e-Signature process to verify identity and gain consent to obtain medical data should be at least as safe, if not safer, than the current wet signature system used to verify identify and obtain and demonstrate authentic and fully informed consent.

APPENDIX 1 - e-Signatures and Legislation.

e-Signatures have been successfully employed in many different applications over the last 15 years and their use is considered normal practice in many areas including law and contracts. The legislation that supports the growth in the application of e-Signatures also dates back some 15 years and similar legislation has appeared throughout developed countries enabling their use in all areas of e-commerce.

The main pieces of legislation legitimising the use of e-Signatures in the UK are as follows:

1) **EU Directive 1999/93/EC of the European Parliament and of the Council on A Community Framework for Electronic Signatures**:

This was the first piece of major legislation and the Directive stated that "an advanced electronic signature based on a qualified certificate created by a secure-signature-creation device satisfies the legal requirements of a signature in relation to data in electronic form in the same manner as a handwritten signature satisfies those requirements in relation to paper-based data."

The advanced electronic signature is defined as an electronic signature, which meets the following requirements:

a) it is uniquely linked to the signatory;

b) it is capable of identifying the signatory;

c) it is created using means that the signatory can maintain under their sole control; and

d) it is linked to the data to which it relates in such a manner that any subsequent change of the data is detectable.

N.B. From the 1 July 2016 this directive will be replaced by the 'Regulation on electronic identification and trust services for electronic transactions in the internal market' (commonly referred as "e-IDAS" Regulation) which was published in the Official Journal of the EU on 28 August 2014.

2) **Electronic Communications Act 2000:**

Sections 1- 6 regulate the use of cryptographic services in the UK.

Section 7 - 10 confirms the legal status of electronic signatures effectively making them admissible in a court of law.

3) Electronic Signatures Regulation 2002:

The Electronic Signatures Regulations 2002 implements Directive 1999/93/EC (see above).

The provisions of this Directive relating to the admissibility of electronic signatures as evidence in legal proceedings were implemented by Section 7 of the Electronic Communications Act 2000.

To achieve a level of certainty and admissibility in a court of law, an electronic signature compared to a handwritten signature needs to be:

- unique to the signatory;
- created using means within a signatory's sole control;
- capable of being linked to the relevant document or data in such a way that any subsequent changes to that document or data would be detectable.

Case law to date includes:

Bassano v Toft & Ors [2014] EWHC 377 (QB) where The Hon. Justice Popplewell in the Central London County Court, February 2014 ruled that credit agreements regulated by the Consumer Credit Act 1974 can be validly concluded by way of electronic signature;

Golden Ocean v Salgaocar Mining Industries ([2012] 1 Lloyd's Rep 542) Where the Court of Appeal held that electronic communication by multiple emails was "accepted contemporary business practice" and good evidence of the signature of a contract of guarantee.

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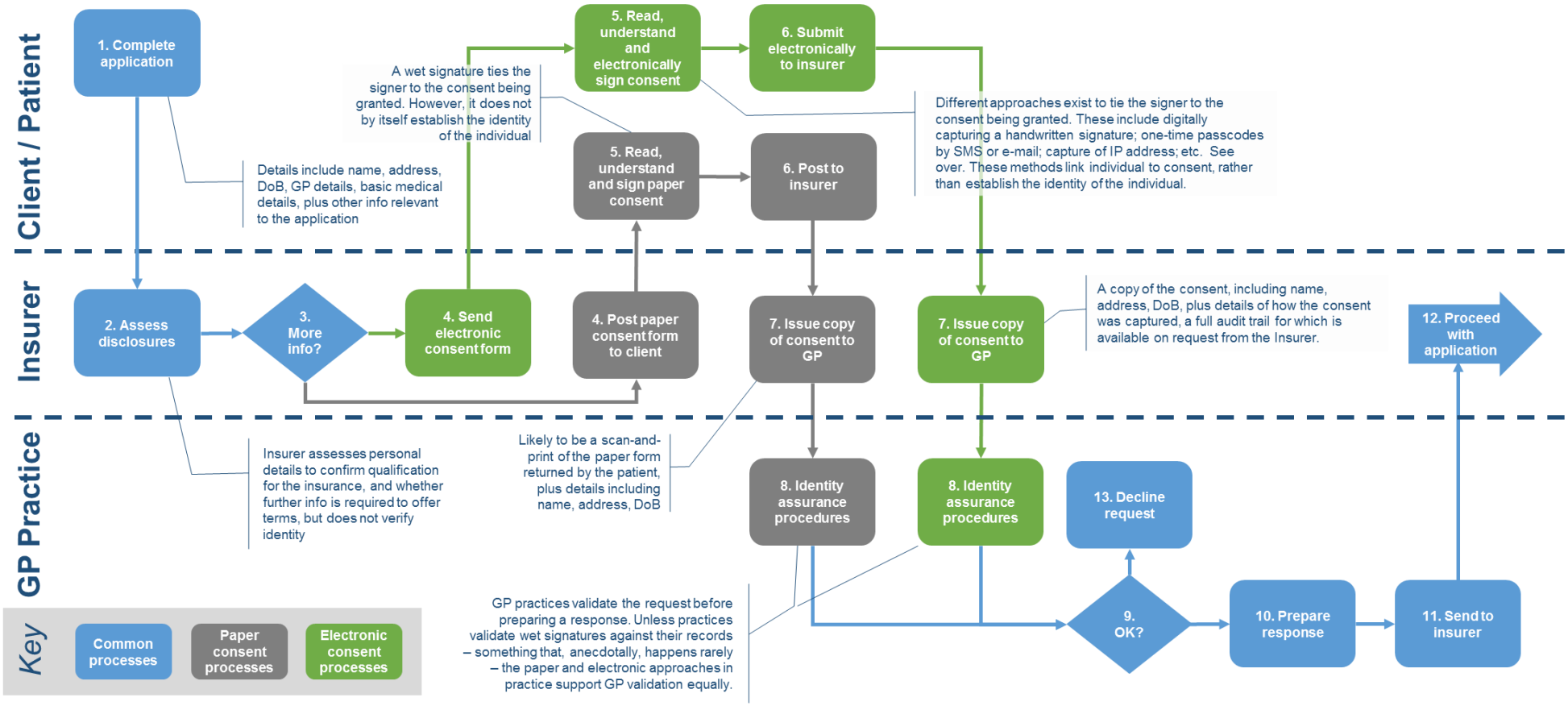
APPENDIX 2 - Comparing e-Signature consent with wet signatures

This diagram shows how consent processes currently supported by wet signatures compare with those supported by e-signatures. It does not imply any particular e-signature service or solution supplier.



Methods of associating signer with consent

Different approaches exist to tie an electronic signer with the consent being granted.

Method	Description
IP address capture	The IP address from which a completed electronic consent form is captured and stored along with the consent being granted. This helps identify the device being used when consent is granted.
One-Time Passcodes	The signer is sent a passcode by SMS and/or e-mail, which they then add to the completed electronic consent form. This shows that the signer is the individual in control of the phone or e-mail address used.
Digital capture of 'handwritten' signature	The signer uses the device on which consent is being captured to create a likeness of their handwritten signature. This might be done with a mouse, stylus or finger, depending on the characteristics of the device, with a varying precision. Doing so associates the individual making the mark with the consent being marked.

In common with most wet signature-based processes, these approaches create an evidential link between the signer and the consent being granted, rather than establishing the identity of the signer.

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APPENDIX 3

The following are examples of evidence demonstrating how consent and authentication can be conveyed. These examples are from proof of concepts for e-Signature processes from two participating organisations.

Access to medical reports

ZURICH

This leaflet tells you why we ask you about your medical history, why we might ask your doctor for medical reports and what we do with the information given to us. It also explains your rights under the Access to Medical Reports Act 1988 or the Access to Personal Files and Medical Reports (Northern Ireland) Order 1991.

Why do you ask me questions about my medical history?

We use the information you give us in your application and reports from your doctor, to help us assess the risk of providing you with the cover you have requested. This then ensures that we are fair to all customers when deciding if we can offer cover and if so, on what terms.

What information will be in the doctor's report?

The medical report your doctor fills in will ask about:

- any tobacco, nicotine replacements, alcohol or drug usage
- details, including providing us with copies of any reports or letters, of any illness, trauma, or referrals for specialist advice or treatment, hospital admissions, consultations with your GP or any other medical adviser, therapist or counsellor. For example, we will ask about;
  - i any history of heart disease, cancer, stroke, diabetes, mental illness, central nervous system diseases, musculoskeletal disease or injury
  - ii the results of any tests or investigations that you've had or any tests or investigations that you are awaiting
  - iii any prescribed medication
  - iv any time off work
- any history of disease in your mother, father, brothers or sisters you've told your doctor about.

The medical report will not ask for any information about:

- negative tests for HIV, hepatitis B or C, isolated or multiple incidences of sexually transmitted diseases unless there are long-term health implications, or any predictive genetic test results.

Your rights under the Access to Medical Reports Act 1988 or the Access to Personal Files and Medical Reports (Northern Ireland) Order 1991.

We may need to apply to your doctor for a medical report and, if we do, we'll need your permission. Your legal rights are:

- You don't have to give your consent, but if you don't we may not be able to proceed. This does not stop you applying elsewhere.
- You can ask to see the report before your doctor returns it to us. If you do, we'll ask your doctor to retain it for 21 days so that you can arrange to see the report. This may cause a delay in processing your application.
- You can ask your doctor for a copy of the report at any time during the 6 months after it has been sent to us.
- You can ask your doctor to amend the report if you consider any aspect of the report to be incorrect or misleading. If your doctor refuses to make the amendments, you may add your comments to the report.
- Your doctor can refuse you access to the report if he feels this would cause physical or mental harm to you or others.

If you have any questions about your rights under the Act or any questions about the process of obtaining, assessing or storing medical information, please contact us at:

Customer Services, Zurich Assurance Ltd, Tricentre One,
New Bridge Square, Swindon, SN1 1HN.
Or call us on 01793 514514.
We are open from Monday to Friday 8.30am to 6pm

Confidentiality of customer information

Zurich Assurance Ltd (Zurich) are committed to ensuring that the way we collect, hold, use and share information about you fully complies with the Data Protection Act 1998. Before signing the Declaration (below) you should refer to the Data Protection statement provided to you when you applied for the policy. This explains how your data will be used. If you would like more information please contact us or ask your adviser.

Declaration

I have read the section headed 'Your rights under the Access to Medical Reports Act 1988 or the Access to Personal Files and Medical Reports Northern Ireland) Order 1991'. I consent to Zurich obtaining medical information from any doctor about anything affecting my physical or mental health and to Zurich obtaining information from other insurers about previous applications I have made for any life, sickness, accident or private medical insurance. I authorise those asked for such information to provide it on the production of a copy of this consent.

(X) I do NOT want to see the medical report before it is returned to Zurich.

( ) I do want to see the medical report before it is returned to Zurich.

Full Name	Chris Kiwomya
Plan number	12345678
Signature	Chris Kiwomya
Date of signature	18-Dec-2014

Once you have signed this form, if you are returning it by post, please return it to;

Freepost RTHA-LBCZ-CRUL
Zurich Assurance Ltd 6, The Tricentre, New Bridge Square, Swindon SN1 1HN

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Chris Kiwomya GRAHAM.bennett@uk.zurich.com Zurich Security Level: Email, Account Authentication (None) Electronic Record and Signature Disclosure: Not Offered ID:	Chris kiwomya Using IP Address: 80.254.155.99	Sent: 12/18/2014 3:04:20 PM GMT Viewed: 12/18/2014 3:05:13 PM GMT Signed: 12/18/2014 3:05:22 PM GMT

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Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

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barney rubble graham.bennett@uk.zurich.com Zurich Security Level: Email, Account Authentication (None) Electronic Record and Signature Disclosure: Not Offered ID:	COPIED	Sent: 12/18/2014 3:05:23 PM GMT

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Envelope Summary Events	Status	Timestamps
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Access to Medical Reports - Important Notes & Declaration

For use with the LV= Flexible Protection Plan

Our Reference	test
Full Name	

The plan will not start until we have assessed and accepted your application, and the first premium has been paid. If you have a birthday while your application is being processed, the terms may differ from those originally quoted. In most instances your payments will be as originally quoted. We may offer you revised terms, but occasionally we may not be able to offer any terms. We may ask you to contact your doctor if we are waiting for reports that we have asked for. If we ask you to come for a medical examination, we will need to share the application information with another company we have authorised. They will make the arrangements for the examination to take place.

We may need to send your application and relevant medical reports to our reassurers for their opinion or agreement of the terms offered. Or, we may need to send them at a later stage for purposes relating to managing the policy. You can get details of general reassurance principles and details of any company we use to assess your application, from our head office. We have a confidentiality policy in place that means we hold your medical information securely and access is limited to authorised individuals who need to see it. You are entitled to ask for a copy of our standard terms and conditions and a copy of your application form at any time.

Access to medical reports

We may need to get medical reports to support your application. Before we can ask any doctor that you have consulted to fill in a report, we need your permission under the Access to Medical Reports Act 1988. Your rights under the act are as follows. You do not need to give your permission, but if you do not, we may not be able to go ahead with your application. This does not prevent you from applying to other companies for insurance. You can ask to see the report before the doctor returns it to us. If this is the case, we will tell the doctor to keep the report for 21 days so that you can arrange to see it. If you have not made arrangements to see the report within this time, your doctor will send the report to us. If you choose not to see the report at this stage, you may ask the doctor for a copy within six months of it being sent to us. We can send a copy of the report to your doctor if you ask to see it at a later date. If you think that any part of the report is not correct or is misleading, you may ask the doctor to amend it. If your doctor refuses to make the amendments, you may ask him or her to attach a statement outlining your views, which will then accompany the report. Your doctor can withhold access to the report if he or she feels that it would cause physical or mental harm to you or others. The medical report your doctor fills in – may ask about the following:

Your current health
Any care, medication or treatment you are currently receiving
The results of referrals or tests you are waiting for.
Any time off work in the last three years.
Your past health.
Details of any relevant illness, trauma, or referrals for specialist advice or treatment, hospital admissions, consultations with your GP or any other medical adviser, therapist or counsellor, in particular whether you have a history of:

- malignancy (cancer), cardiovascular (heart) disease, diabetes, and degenerative (gradually worsening) diseases;
- musculoskeletal disease or injury, for example, arthritis, rheumatism, back problems or any other disorder of the joints or muscles;
- anxiety, depression, neurosis (such as phobias, obsessions and so on), psychosis (a mental disorder where you lose contact with reality), stress or fatigue;
- suicidal thoughts or attempts at suicide; or
- conditions related to drug or alcohol misuse or smoking or chewing tobacco.
- Details of any biopsies, blood tests, electrocardiograms (heart test), height, weight if measured in the last two years, urinalyses (tests on urine), x-rays or other investigations.
- Any blood pressure readings in the last three years.

Any history of disease among your parents or brothers or sisters that you have told your doctor about.

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We have asked your doctor not to reveal information about:

Negative tests for HIV, Hepatitis B or C;
Any sexually-transmitted diseases unless there could be long-term effects on your health;or
Predictive genetic test results unless there is a favourable test result that shows that you have not inherited a condition your family suffers from.

The information you and your doctor provide about your health may results in us:

Refusing to provide insurance;
increasing premiums above standard rates; or
Setting premiums at standard rates.

If you have any questions about your rights under the Act or questions relating to the process of getting, assessing or storing medical information, please write to: LV=, Pynes Hill House, Rydon Lane, Exeter, EX2 5SP.

If LV= need to obtain a report from my doctor:

☑ **I DO NOT want to see the report before it is sent to the company**

☐ **I DO want to see the report before it is sent to LV=**

Declaration

I agree to you asking any doctor I have consulted about my physical or mental health to provide medical information so you may assess my proposal. You may gather relevant information from other insurers about any other applications for life, critical illness, sickness, disability, accident or private medical insurance that I have applied for. I authorise those asked to provide medical information when they see a copy of this consent form. This form allows you to gather medical reports within six months of the start of the plan, or after my death, to support any claim made on the plan proceeds.

This information can also be used to maintain management information for business analysis.

I have read the declaration, Important Notes and information relating to my rights under the Access to Medical Reports Act.

Name	
Signature	D Woodward D Woodward (Dec 23, 2014)
Date	Dec 23, 2014

For any questions please call: 01329 888 715

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